**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| In re the application of: Stephen C. Knight | Attorney Docket No.: VEK-001.01 |
| Serial No.: 09/938,295 | Group Art Unit: 3626 |
| Filed: August 23, 2001 | Examiner: Porter, Rachel |
| For: *Recruiting a Patient Into a Clinical Trial* | |

# APPEAL BRIEF

To the Commissioner for Patents:

Appellant submits this brief in support of the appeal initiated by a Notice of Appeal filed on July 6, 2009 and petitions for a five-month extension of time in which to file this brief. The fees required to file the brief and petition have been paid electronically.

***(1) Real Party in Interest***

The real party in interest in this appeal is Quintiles, Inc., Assignee of record.

***(2) Related Appeals and Interferences***

There are no other appeals or interferences known to Appellant, the Attorneys/Agents or record, or the Assignee which will directly affect or be directly affected by or have a bearing on the Board's decision in the present appeal. Claims 34-44 were copied from claims 22-32 of U.S. Patent Application No. 11/450,450, filed June 12, 2006 and published October 12, 2006 as US2006/0229916-A1. The '450 application has not yet been examined.

***(3) Status of Claims***

The application has a total of forty-four claims. Of these, claims 2-4, 9-12, 17, and 19-44 are pending and claims 1, 5-8, 13-16, and 18 are canceled. Claims 2-4, 9-12, 17, and 19-44 stand finally rejected and are on appeal.

***(4) Status of Amendments***

No amendment was filed after the final rejection that led to this appeal.

***(5) Summary of Claimed Subject Matter***

The subject matter of independent claim 17 is a method of recruiting a patient into a clinical trial (Page 1, Title: "Recruiting a patient into a clinical trial."). The method includes serving from a server to the patient (Page 15, lines 10-15; Fig. 29, element 2908) a questionnaire (Page 11, lines 12-13; Page 14, lines 21-27; Fig. 2, element 1; Fig. 27, element 2702) that includes at least one clinical trial eligibility question (Page 11, lines 16-18); receiving at the server from the patient patient-specific data that includes an answer to the at least one clinical trial eligibility question (Page 6, line 25); sending the patient-specific data from the server to a security layer (Page 17, lines 8-11; Fig. 29, elements 2908 and 2910); sending the patient-specific data from the security layer to a matcher (Page 17, lines 11-12); preventing direct communication between the server and the matcher (Page 8, lines 18-19; Fig. 29, element 2910); accessing criteria of one or more clinical trials (Page 8, lines 9-11; Page 11, line 24; Page 18, line 9; Fig. 30, element 3004); determining using the matcher whether the patient-specific data satisfies the criteria of one or more clinical trials (Page 8, lines 9-11; Page 16, lines 27-28); inviting the patient to participate in a clinical trial for which the criteria have been determined to be satisfied, if

any (Page 12, lines 20-21; Fig. 10, element 1004); and if the patient chooses to participate, registering the patient in a database (Page 11, lines 2-3).

The subject matter of independent claim 19 is a computer system for recruiting a patient into a clinical trial (Page 1, Title: "Recruiting a patient into a clinical trial."). The system includes components configured as at least: a server (Page 15, lines 10-15; Fig. 29, element 2908) which: requests patient-specific data from the patient (Page 11, lines 12-13; Page 14, lines 21-27; Fig. 27, element 2702), the patient-specific data requested including clinical trial eligibility data (Page 11, lines 16-18), collects the patient-specific data from the patient (Page 6, line 25); and sends match result data to the patient (Page 14, lines 28-29; Fig. 28, element 2802); a matcher (Page 16, lines 27-28) responsive to the patient's clinical trial eligibility data and to trial-specific criteria corresponding to the clinical trial (Page 16, lines 27-28) to: determine whether a match exists between the patient and the clinical trial (Page 8, lines 9-11); and generate the match result data (Page 8, line 18); and a security layer (Page 15, lines 11-12; Fig. 29, element 2910) which: prevents direct communication between the server and the matcher (Page 8, lines 18-19; Fig. 29, element 2910); receives the patient-specific data from the server (Page 17, lines 8-11; Fig. 29, elements 2908 and 2910); sends the patient's clinical trial eligibility data to the matcher (Page 17, lines 11-12); and receives the match result data from the matcher and sends it to the server (Page 17, lines 12-13).

The subject matter of independent claim 23 is a method of determining whether a patient is a candidate for a clinical trial (Page 1, Title: "Recruiting a patient into a clinical trial."). The method includes serving a questionnaire (Fig. 2, element 1) from a server to a

patient through a patient interface (Page 15, lines 10-15; Fig. 29, element 2908); receiving at the server patient eligibility data submitted by the patient in response to the questionnaire (Page 6, line 25); sending the patient eligibility data from the server to a security layer (Page 17, lines 8-11; Fig. 29, elements 2908 and 2910); sending the patient eligibility data from the security layer to a matcher (Page 17, lines 11-12); in the matcher: (a) determining whether a match exists between the patient and the clinical trial by comparing the patient eligibility data to a set of trial criteria specific for the clinical trial (Page 8, lines 9-11; Page 16, lines 27-28); and (b) returning match result information to the security layer (Page 17, lines 12-13); sending to the server the match result information thus returned from the security layer (Page 17, lines 12-13); and serving to the patient through the patient interface the match result information thus sent to the server (Page 8, lines 23-24; Fig. 7, element 702; Fig. 28, element 2802).

The subject matter of independent claim 31 is a method of determining whether a patient is a candidate for a clinical trial (Page 1, Title: "Recruiting a patient into a clinical trial."). The method includes serving a first questionnaire (Fig. 2, element 1) from a server to a patient through a patient interface (Page 15, lines 10-15; Fig. 29, element 2908); receiving at the server a first set of patient eligibility data submitted by the patient in response to the first questionnaire (Page 6, line 25); sending the first set of patient eligibility data from the server to a security layer (Page 17, lines 8-11; Fig. 29, elements 2908 and 2910); sending the first set of patient eligibility data from the security layer to a matcher (Page 17, lines 11-12); in the matcher: (a) determining whether a match exists between the patient and the plurality of clinical trials by comparing the first set of patient

eligibility data to a set of generic trial criteria generic to a plurality of clinical trials (Page 8, lines 9-11; Page 16, lines 27-28); and (b) returning generic match result information to the security layer (Page 17, lines 12-13); if a match exists between the patient and the plurality of clinical trials (Page 11, lines 13-14): serving a second questionnaire from the server to the patient through the patient interface (Page 11, lines 15-18; Fig. 2, elements 3,4); receiving at the server a second set of patient eligibility data submitted by the patient in response to the second questionnaire (Page 6, line 25); sending the second set of patient eligibility data from the server to the security layer (Page 17, lines 8-11; Fig. 29, elements 2908 and 2910); sending the second set of patient eligibility data from the security layer to the matcher (Page 17, lines 11-12); in the matcher: (a) determining whether a match exists between the patient and the one clinical trial by comparing the second set of patient eligibility data to a set of specific trial criteria specific to one of the plurality of clinical trials (Page 8, lines 9-11; Page 11, lines 18-19; Page 16, lines 27-28); and (b) returning specific match result information to the security layer (Page 17, lines 12-13); if a match exists between the patient and the one clinical trial (Page 11, line 1): sending information about the one clinical trial from the security layer to the server (Page 17, lines 12-13); and serving the clinical trial information to the patient through the patient interface (Page 8, lines 23-24; Page 11, lines 1-2; Fig. 7, element 702; Fig. 28, element 2802).

The subject matter of independent claim 34 is a system including a computer memory (Page 7, lines 19-20) for storing information indicating whether notice of one or more clinical studies associated with a particular disease condition is desired (Fig. 26, element 2602) and registration information that indicates at least a geographic location,

said disease condition of interest, and contact information (Page 6, lines 19-27; Page 18, lines 18-19). The memory stores computer instructions for presenting a web page questionnaire to a user (Fig. 29, element 2908). The system further includes means for storing in said memory responses to a questionnaire, a means-plus-function limitation as permitted by 35 U.S.C. § 112, sixth paragraph, which corresponds (solely for the purpose of the present appeal) to a security layer (Page 15, lines 11-12; Fig. 29, element 2910) which: prevents direct communication between a web page server and the computer memory (Page 8, lines 18-19; Fig. 29, element 2910); receives the patient-specific data from the server (Page 17, lines 8-11; Fig. 29, elements 2908 and 2910); sends the patient's clinical trial eligibility data to the memory (Page 17, lines 11-12); and receives the match result data from the memory and sends it to the server (Page 17, lines 12-13).

***(6) Grounds of Rejection to be Reviewed on Appeal***

Appellant submits two grounds of rejection for review:

A. that the subject matter of claims 34-44 is anticipated under 35 U.S.C. § 102(e) by U.S. Pre-Grant Application Publication No. 2002/0002474-A1 to Michelson et al. ("Michelson"); and

B. that the subject matter of claims 2-4, 9-12, 17, and 19-33 is unpatentable under 35 U.S.C. § 103(a) over Michelson in view of PCT Publication No. WO 01/93160-A1 to Reddy et al. ("Reddy").

***(7) Argument***

Two fundamental problems necessitate this Appeal Brief.

First, the Examiner ascribes to the Michelson provisional far more than its meager disclosure actually describes. The vague and sketchy passages in Michelson's provisional, when read without hindsight, simply do not disclose all elements of Appellant's claims. The Examiner seems to suggest that one may impute greater meaning to Michelson's provisional disclosure in light of Michelson's nonprovisional disclosure. But such a position has no basis in law. The question of anticipation must be asked as of Appellant's effective filing date. On that date, Michelson's nonprovisional application did not exist.[1] Its content is therefore irrelevant. The Examiner may cite the nonprovisional application publication only to the extent it incorporates matter from the provisional. The best way to do that, and to avoid any taint of hindsight from the nonprovisional disclosure, is to cite directly to Michelson's provisional application and simply ignore the nonprovisional application.

Second, the Examiner entirely ignored 9 of 13 specific arguments Appellant made in the Sep. 12, 2008 response. For the rest, the Examiner offered perfunctory dismissals that did not address the substance of Appellant's arguments. The Examiner did not fulfill the duty to answer all material traversed. "Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it." M.P.E.P., § 707.07(f).

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[1] Michelson's provisional application no. 60/178,634 was filed Jan. 28, 2000. Appellant's provisional application no. 60/227,484 was filed Aug. 24, 2000. Michelson's nonprovisional application no. PCT/US01/02936 was filed Jan. 29, 2001. Appellant's present nonprovisional application no. 09/938,295 was filed Aug. 23, 2001.

Claim-specific arguments follow.

A. Claims 34-44 are not anticipated by Michelson.

i. Michelson never presented these claims in US 2002/0002474 A1.

The Examiner's entire explanation of anticipation was:

> Claims 34-44 have been copied by applicant directly from (US 2002/0002474 A1) to prematurely evoke interference. Therefore, claims 34-44 are clearly anticipated by claims 22-32 of the Michelson publication.

The Examiner is incorrect. Those claims were not copied from Michelson US 2002/0002474-A1. Instead, they were copied from US 2006/0229916-A1, which is a continuation of US 2002/0002474-A1. Michelson never presented these claims in 2002/0002474 and only first presented them in 2006/0229916, long after Appellant's priority and nonprovisional dates. The first presentation and publication of those claims is therefore not citable as prior art. The Examiner cannot reject the claims out-of-hand simply because they were copied from an after-filed application.

The Examiner appears to assume instead that the claims must be supported by Michelson's provisional and nonprovisional applications, just because Michelson filed them in a continuation. But these claims have never been examined for adequate support by Michelson's disclosures. And in fact, Michelson's provisional does not support the claims, as explained below.

ii. Michelson's provisional application does not disclose all limitations.

Claim 34 requires, among other things, that the computer memory store "information indicating whether notice of one or more clinical studies associated with a particular disease condition is desired."

Appellant's provisional application supports this limitation. See, for example, Fig. 2 on p. 9 of Appellant's provisional application, which shows an example of a questionnaire allowing patients to elect whether they want to be contacted about future clinical trials or instead to remain anonymous.

Michelson's provisional, in contrast, does not support the limitation. The only patient information Michelson's provisional application describes storing is "`relevant clinical data, zip code of residence, and e-mail addresses`" (p. 7, lines 13-14). Michelson does not disclose storing information about a patient's interest in being contacted. The system described in Michelson's provisional application is one in which the investigators or drug companies mine the patient database to identify candidate patients, whom they then contact unilaterally. Michelson does not address the patient's desire in this regard, only the investigator's and drug company's.

Appellant made exactly this argument in the response filed Sep. 12, 2008, and the Examiner never responded to it. All the Examiner wrote in the "Response to Arguments" section of the final rejection was:

> In response, the Examiner respectfully disagrees [with] the Applicant's statement that the Michelson provisional does not support the claims. As to applicant's assertion that the Michelson provisional does not describe patient interaction or communication using a computer, the Applicant has provided examples from the provisional application (see page 8, first and second paragraphs) which describe website access to the general public, and provide patients a chance to interact with other patient and investigators. The Michelson provisional further describes an additional security layer which allows communication with patients and investigators. (Page 9, lines 1-3)
>
> It should be noted that the non-provisional application need not be verbatim copy of the provisional. Furthermore, the current rejection is based upon Michelson et al (US 2002/0002474 A1).

Also, while the Applicant's newly added claims 34-44 might be supported by the Applicant's specification, they also represent a shift in the scope of the originally presented invention.

Yet nothing in the cited passages of Michelson's provisional application discloses the claim limitation of storing "information indicating whether notice of one or more clinical studies associated with a particular disease condition is desired."

The first and second paragraphs from page 8 of Michelson's provisional application are:

> The system also includes a web site 320 through which a variety of information may be accessed through decision support software that is used to access the various databases. The web site contains a patient registry that is organized both therapeutically and geographically so that site selection decisions can be made based upon detailed knowledge of a specific patient's availability. There also are multiple Internet health care portals so that an Internet patient recruitment program that is study and site-specific can be initiated. The site includes health demographics information about the general populations proximate to an investigator's location. The web site also includes industry specific news, chat rooms related to industry specific topic and relevant clinical trials, periodic reports of results developed from patient satisfaction and outcome panels, virtual seminars on issues such as changes in FDA regulations, new categories of drugs, etc.
>
> The web site 320 has three tiers of access. Tier 1 is available to the general public, and contains the general information about the pharmaceutical industry, industry specific news, and clinical trials. Tier 1 also contains chat rooms that will give patients a location to ask questions of research investigators and of other patients. Tier 2 is available to authorized users, such as those confirmed to be in the pharmaceutical industry. These users have access to the databases, except that the

> identity of investigators, site names and/or patient names are not available. This level of access also provides simple e-mail and fax tools to enable the user to start planning the investigator/patient recruitment process. Tier 3 permits access to the databases, and are generally for the sponsors of clinical trials. Through the proprietary software, tier 3 permits the sponsor access to the identities of the investigators, to the historic investigator trial performance information, and to means with which to communicate with both investigators and patients. Communication with patients protects the patients' privacy.

At most, this disclosure states that "Tier 3" users have access to means with which to communicate with both investigators and patients. No part of Michelson's provisional disclosure describes storing information indicative of whether the patient desires contact.

The Examiner mis-characterized and over-generalized Appellant's argument. The Examiner described Appellant's argument as "applicant's assertion that the Michelson provisional does not describe patient interaction or communication using a computer." Appellant argued no such thing. Rather, Appellant argued, and argues here again, that Michelson's provisional fails to disclose a specific element of the claim. The Examiner has not responded to this argument.

The Examiner then stated: "It should be noted that the non-provisional application need not be verbatim copy of the provisional." While Appellant certainly agrees with that statement in the abstract, it certainly does not follow that the present rejections can stand where Michelson's provisional application fails to disclose claim elements. Any difference at all between Michelson's provisional and nonprovisional

disclosure must be disregarded for present purposes. Rejections must not refer to Michelson's nonprovisional application, unless the Examiner then points out the identical disclosure in Michelson's provisional application.

The claim requires a limitation that is not disclosed in Michelson, so the rejection should be reversed.

B. Claims 2-4, 9-12, 17, and 19-33 are patentable over Michelson in view of Reddy.

The Examiner did not contest Appellant's showing of support in his provisional application. Rather, the Examiner maintained the position that Michelson's provisional application included all nonprovisional disclosure relied upon in making the rejection. But again, as for the anticipation rejection of claims 34-44, the Examiner ascribed far more to Michelson's provisional disclosure than is warranted.

i. Claims 19 and 2-4, 9-12, 20-22, 32, and 33.

a) Michelson's provisional application does not teach a server which requests or collects patient-specific data from the patient.

The Examiner never responded to this argument, which was presented on pages 12-14 of the Sep. 12, 2008 response. Appellant therefore repeats it here.

Michelson's provisional application describes no interaction between a patient and a computer system except the "`Tier 1`"-level access discussed in the second full paragraph of page 8, which includes "`general information about the pharmaceutical industry, industry specific news, and clinical trials`" and also provides "`chat rooms that will give patients a`

location to ask questions of research investigators and of other patients." The Michelson provisional application never describes requesting or collecting any patient-specific data from a patient that is subsequently used by the matcher. While the Michelson provisional application does describe "account sign-up, management, demographics capture, and personalization of target audiences" in the second full paragraph of page 9, it never describes the collection of any data that is subsequently used for matching, nor does it even specify that such "account sign-up" etc. is carried out by a patient. Indeed, the end of the paragraph states that the system is customized to particular "sponsors," which indicates that the users who are setting up accounts are from pharmaceutical companies sponsoring clinical trials, not patients seeking recruitment. And while the provisional application mentions that its software "enables patients to identify clinical trials for which they may enroll" at p. 10, lines 4-5, this disclosure simply refers to the general public's ability to browse "general information about . . . clinical trials" available through the Tier-1 access discussed on page 8. It does not suggest any kind of matching that is responsive to clinical trial eligibility data collected from a patient.

Moreover, Michelson expressly identifies the sources of patient data, in the first full paragraph of p. 7 of his provisional application, none of which is disclosed as being patient-derived:

> [The patient] database is created through solicitations in advertisements on other Internet sites, through collection of billing and other data

> from the physician practice management systems of the physician investigators who have private practices, and through managed care organizations, employers, hospital systems, prescription benefit manager, disease management companies, disease advocacy groups, and physician practice management companies. Further information may be collected from pathology labs to provide more detail about the disease status of oncology patients.

Furthermore, in referring to "collection of billing and other data" from management systems, managed care organizations, employers, hospital systems, etc., Michelson clearly espouses his intent to gather patient data in bulk from organizations that maintain large repositories of patient data, rather than by piecemeal one-on-one interactions with patients.

b) Michelson's provisional application does not teach a server which sends match result data to the patient.

The Examiner never responded to this argument, which was presented on page 14 of the Sep. 12, 2008 response. Appellant therefore repeats it here.

Michelson never sends match result data to the patient. This must be so because Michelson's system does not communicate anything to a patient other than the "general information about the pharmaceutical industry, industry specific news, and clinical trials" and chat rooms (p. 8, last paragraph) accessible to patients through Tier-1 access. Rather, it is the investigators who conduct the searches, obtain the results, and decide whether to contact patients; the system "enables clinical trial investigators and sponsors to identify individuals in the patient database who have a

likelihood of qualifying for a particular clinical trial" (p. 9, last two lines). *Patients* do not carry out this identification. Indeed, they cannot, because Michelson's provisional disclosure restricts database access to only Tier 2 users "confirmed to be in the pharmaceutical industry" and Tier 3 users, who are "sponsors of clinical trials" (p. 8, last paragraph). Thus, Michelson's provisional system does not conduct matches at the behest of patients and does not communicate any match result data to them.

c) Michelson's provisional application teaches away from the claimed security layer.

The Examiner responded to this argument dismissively by stating:

> Michelson discloses both in the provisional (pgs. 8-9) and in the US 200[2]/0002474 (par. 80-83, 185) [] tier access for security purposes. Michelson also provides an explanation of a layering system in the inventive system. (Figure 3- provisional)

First, the Examiner must consider Michelson's provisional application by itself and without any regard to Michelson's nonprovisional application. The Examiner accepts Appellant's priority argument, so Michelson's nonprovisional application should simply be thrown out. The references to Michelson's nonprovisional application are irrelevant.

Second, the issue is not whether Michelson teaches away from any sort of security arrangement. The issue is rather whether Michelson teaches away from the security layer specifically required by the claims. Claim 19 specifically requires a security layer that "prevents direct communication between the server and the matcher." The matcher operates in the trials database, as disclosed in Appellant's provisional application on p.16,

last paragraph. Thus the claim limitation inherently requires that direct communication between the server and the database be prevented.

Michelson's provisional application states exactly the opposite requirement. In the very first paragraph (p. 1, line 6) Michelson's provisional explains that its system is designed "to enable appropriate parties **access and use of the secure databases**" (emphasis added). Michelson's provisional application repeatedly states that the system is designed to give authorized users access to the databases (*see*, for example, p. 8, last paragraph, and p. 10, last paragraph).

Yet the claimed security layer specifically excludes such database access by preventing direct communication between the server and the matcher. By requiring that authorized users have direct access to the secure databases, Michelson's provisional application unambiguously deters the reader from interposing the claimed security layer.

So even if Michelson discloses some security measures, or even a layered approach to system access as the Examiner argues, Michelson still unambiguously imposes a requirement fundamentally incompatible with the claimed system. Grafting the claimed security layer onto Michelson's provisional would destroy Michelson's "access" requirement and so would not have been considered obvious. The mere fact that parts of Michelson's disclosure are not inconsistent with the claimed security layer is irrelevant. The reference "must be considered in its entirety, including disclosures that teach away from the claims." M.P.E.P., § 2141.02, section VI.

It is similarly irrelevant that the Examiner cited a separate reference for the claimed security layer. A secondary reference simply cannot cure Michelson's express teaching away.

Also irrelevant are the Examiner's persistent references to Michelson's nonprovisional application. The obviousness inquiry must address the state of the art at the time the invention was made. As of Appellant's provisional filing date (Appellant reserves the right to show that invention occurred earlier), Michelson's nonprovisional application did not exist. It is simply not citable as prior art to Appellant's claims.

ii. Claim 17

Appellant explained (on p. 15 of the Sep. 12, 2008 response) that arguments analogous to arguments (a) and (c) given above for claim 19 apply to claim 17. The Examiner did not respond to these arguments.

Appellant also argued that Michelson's provisional application does not teach registering a patient in a database *after* clinical trial criteria have been determined to be satisfied, as required by claim 17.

The Examiner dismissed this argument on the ground that claim 17 does not recite this feature (i.e., registering *after* criteria are determined to be satisfied). The Examiner is mistaken. Claim 17 recites, in pertinent part:

> determining using the matcher whether the patient-specific data satisfies the criteria of one or more clinical trials;
>
> inviting the patient to participate in a clinical trial for which the criteria have been determined to be satisfied, if any; and
>
> if the patient chooses to participate, registering the patient in a database.

True, claim 17 does not use the word "after." But that temporal ordering is inherent in the claim. That is, the ordering is necessarily present, because there is no interpretation of claim 17 that does not require registering after determining. The "inviting" step can occur only once the determination has been made with respect to a particular trial. And the registration can take place only after the patient chooses to participate. Therefore registering must necessarily take place after determining.

The Examiner did not respond on the merits of the argument, so Appellant repeats them here.

Michelson's provisional application describes building up a patient database *before* searching that database to identify patients located near an investigator. Michelson never describes sending patient-specific data to a database only after determining whether a match exists between a patient and a clinical trial.

Moreover, Michelson's nonprovisional disclosure underscores his express requirement that patients first be registered *before* any access to clinical trials is provided. *See*, for example, Figs. 2A-2B, in which one of the benefits of registration is to "`get trial information and find out how you can be considered for participation in clinical trials,`" and paragraphs [0082]-[0083], which explain that only registered users may attempt to qualify for clinical trials. For example, in paragraph [0082] Michelson states that "`demographic information about each registered person is stored in the database`" and then states that as a person "`attempt[s] to qualify for participation in various clinical studies, system 100 collects and stores`

additional information about the persons represented in the subject database," meaning that a person is *already registered* in the database when seeking to qualify for a clinical trial. In contrast, the claim specifies that registration occurs *after* clinical trial criteria have been determined to be satisfied. The difference is non-trivial; Appellant's claimed system affords a greater deal of privacy to patients compared to Michelson's system by allowing them to attempt a trial match before revealing any personal identification.

iii. Claims 23-30

Appellant explained (p. 16 of the Sep. 12, 2008 response) that arguments analogous to arguments (a) and (b) given above for claim 19 apply to claim 23. The Examiner did not respond to these arguments.

iv. Claims 25-28, additional argument

Appellant explained (p. 16 of the Sep. 12, 2008 response) that Michelson's provisional application does not disclose registering a patient in a database after a match has been determined to exist, for reasons analogous to those given above for claim 17. The Examiner did not address the rejection with respect to claims 25-28.

v. Claim 31

Appellant explained (p. 16 of the Sep. 12, 2008 response) that arguments analogous to arguments (a) and (b) given above for claim 19 apply to claim 23. The Examiner did not respond to these arguments.

Appellant also argued that Michelson's provisional application does not teach conducting a second match operation for a particular trial if a first match is determined to exist for multiple trials.

The Examiner responded to this argument as follows:

> The Michelson provisional discloses a multi-step screening process. (pg. 9, par. 1-4 of Provisional application)[.] Moreover, the Michelson reference which was relied upon for the rejection discloses a multiple step screening process to match individuals to clinical trials (Figure 20, par. 168-170, 172).

The Examiner's comments do not address the claim limitations. The claim does not vaguely recite a "multiple step screening process." The claim requires a two-stage match procedure in which a first set of patient eligibility data is compared to general trial criteria for a plurality of trials, and then, if a match exists, a second set of patient eligibility data is compared to specific trial criteria for one trial. The second match is tested only if the first match exists, and the patient is given information about the one trial only if both matches exist.

Michelson's provisional application does not describe this process. The Examiner cited the following paragraphs from Michelson (pg. 9, par. 1-4):

> Communications between users of the web site and through e-mails are secure through authentication, encryption, remote access and digital certificates. Other methods of securing the data will be known to those skilled in the art, and are within the scope of this invention.
>
> The system includes software that supports account sign-up, management, demographics capture, and personalization of target audiences. A core personalization and registration infrastructure supports ad-hoc user properties, profile, and behavioral data collection, content targeting,

> useful site and usage reporting, and specified user views. The views provide the specific information each sponsor needs, and ensures confidential and proprietary data is shielded from competitors.
>
> The software includes proprietary database matching that enables a comparison of the participant profile to the trials protocol criteria. For example, templates are established for certain protocols and performing database matching to compare this information against the participant entered data.
>
> The inventive system includes software that enables users to sort and prioritize data based on multiple criteria. For example, the inventive system software enables sponsors to produce lists of clinical trial investigators ranked by number of trials conducted in a particular therapeutic area, relative performance, health plan affiliations, prescribing behavior, etc. The inventive system software enables clinical trial investigators and sponsors to identify individuals in the patient database who have a likelihood of qualifying for a particular clinical trial and/or are proximate to an investigator's site. Moreover, the inventive system software facilitates the communication and coordination between sponsors and clinical trial investigators relating to the budgeting, contracting, obtaining regulatory documents, and other administrative aspects initiating clinical trials. Finally, the inventive system software enables patients to identify clinical trials for which they may enroll.

There is no discussion here of the claimed two-stage match procedure. Michelson's provisional discusses database matching for comparing a participant profile to trials protocol criteria. But the detailed two-step matching process required by claim 31 is not disclosed. The combination of Michelson and Reddy therefore does not meet all limitations of the claim.

And, as noted above, the Examiner should not make any reference at all to disclosure in Michelson's nonprovisional application. It is not prior art.

C. Summary of Arguments.

Appellant's 13 arguments are listed here for the Examiner's convenient reference:

1. Claims 34-44 are not anticipated by Michelson because Michelson's provisional application does not disclose that the computer memory stores "information indicating whether notice of one or more clinical studies associated with a particular disease condition is desired."

2. Claims 19 and 2-4, 9-12, 20-22, 32, and 33 are not unpatentable over Michelson in view of Reddy because Michelson's provisional application does not teach a server which requests or collects patient-specific data from the patient.

3. Claims 19 and 2-4, 9-12, 20-22, 32, and 33 are not unpatentable over Michelson in view of Reddy because Michelson's provisional application does not teach a server which sends match result data to the patient.

4. Claims 19 and 2-4, 9-12, 20-22, 32, and 33 are not unpatentable over Michelson in view of Reddy because Michelson's provisional application teaches away from the claimed security layer.

5. Claim 17 is not unpatentable over Michelson in view of Reddy because Michelson's provisional application does not teach a server which requests or collects patient-specific data from the patient.

6. Claim 17 is not unpatentable over Michelson in view of Reddy because Michelson's provisional application teaches away from the claimed security layer.

7. Claim 17 is not unpatentable over Michelson in view of Reddy because Michelson's provisional application does not teach registering a patient in a database *after* clinical trial criteria have been determined to be satisfied.

8. Claims 23-30 are not unpatentable over Michelson in view of Reddy because Michelson's provisional application does not teach a server which requests or collects patient-specific data from the patient.

9. Claims 23-30 are not unpatentable over Michelson in view of Reddy because Michelson's provisional application does not teach a server which sends match result data to the patient.

10. Claims 25-28 are not unpatentable over Michelson in view of Reddy because Michelson's provisional application does not disclose registering a patient in a database after a match has been determined to exist.

11. Claim 31 is not unpatentable over Michelson in view of Reddy because Michelson's provisional application does not teach a server which requests or collects patient-specific data from the patient.

12. Claim 31 is not unpatentable over Michelson in view of Reddy because Michelson's provisional application does not teach a server which sends match result data to the patient.

13. Claim 31 is not unpatentable over Michelson in view of Reddy because Michelson's provisional application does not teach conducting a second match operation for a particular trial if a first match is determined to exist for multiple trials.

***(8) Claims Appendix***

See pages 25-32 of this Appeal Brief.

***(9) Evidence Appendix***

See page 33 of this Appeal Brief.

***(10) Related Proceedings Appendix***

See page 34 of this Appeal Brief.

## CONCLUSION

For the reasons given above, Appellant asks that the rejection of claims 2-4, 9-12, 17, and 19-44 be reversed.

Respectfully submitted,
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***(8) Claims Appendix***

1. (canceled)

2. The system of claim 19, wherein the server communicates with the patient through a patient interface that comprises an HTML-encoded web page.

3. The system of claim 19, further comprising a patient database in which the patient-specific data is stored.

4. The system of claim 19, further comprising a clinical trial database, in which the set of trial-specific criteria is stored.

Claims 5-8 (canceled)

9. The system of claim 19, wherein the patient-specific data comprises answers to a questionnaire.

10. The system of claim 19, further configured to send at least a portion of the patient-specific data to the clinical trial.

11. The system of claim 19, wherein the match result data comprises at least one of clinical trial contact and location information, and the server is configured to send the match result data to the patient.

12. The system of claim 19, wherein the patient-specific data comprises at least one of disease of concern, demographic data, drug classes of interest, prior therapies, specific drugs of interest, years since diagnosis, stage of disease, phase of clinical trial, and concomitant diseases.

Claims 13-16 (canceled)

17. A method of recruiting a patient into a clinical trial, the method comprising:

serving from a server to the patient a questionnaire that includes at least one clinical trial eligibility question;

receiving at the server from the patient patient-specific data that includes an answer to the at least one clinical trial eligibility question;

sending the patient-specific data from the server to a security layer;

sending the patient-specific data from the security layer to a matcher;

preventing direct communication between the server and the matcher;

accessing criteria of one or more clinical trials;

determining using the matcher whether the patient-specific data satisfies the criteria of one or more clinical trials;

inviting the patient to participate in a clinical trial for which the criteria have been determined to be satisfied, if any; and

if the patient chooses to participate, registering the patient in a database.

18. (canceled)

19. A computer system for recruiting a patient into a clinical trial, the system comprising components configured as at least:

a server which:

requests patient-specific data from the patient, the patient-specific data requested including clinical trial eligibility data;

collects the patient-specific data from the patient; and

sends match result data to the patient;

a matcher responsive to the patient's clinical trial eligibility data and to trial-specific criteria corresponding to the clinical trial to:

determine whether a match exists between the patient and the clinical trial; and

generate the match result data; and

a security layer which:

prevents direct communication between the server and the matcher;

receives the patient-specific data from the server;

sends the patient's clinical trial eligibility data to the matcher; and

receives the match result data from the matcher and sends it to the server.

20. The system of claim 19, wherein the system comprises at least two computers.

21. The system of claim 20, wherein the security layer runs on one of the computers, and the matcher runs on another computer.

22. The system of claim 3, wherein the security layer is so configured as to send the patient-specific data to the patient database for storage.

23. A method of determining whether a patient is a candidate for a clinical trial, comprising:

serving a questionnaire from a server to a patient through a patient interface;

receiving at the server patient eligibility data submitted by the patient in response to the questionnaire;

sending the patient eligibility data from the server to a security layer;

sending the patient eligibility data from the security layer to a matcher;

in the matcher:

determining whether a match exists between the patient and the clinical trial by comparing the patient eligibility data to a set of trial criteria specific for the clinical trial; and

returning match result information to the security layer;

sending to the server the match result information thus returned from the security layer; and

serving to the patient through the patient interface the match result information thus sent to the server.

24. The method of claim 23, further comprising serving at least one of clinical trial contact and location information to the patient through the patient interface.

25. The method of claim 23, further comprising serving a registration questionnaire to the patient through the patient interface after a match has been determined to exist between the patient and the clinical trial.

26. The method of claim 25, further comprising receiving a set of registration information from the patient.

27. The method of claim 26, further comprising adding the registration information to a patient database.

28. The method of claim 26, further comprising sending at least part of the set of registration information to the clinical trial.

29. The method of claim 23, further comprising comparing, in the matcher, the patient eligibility data to a second set of trial criteria and determining whether a match continues to exist between the patient and the clinical trial.

30. The method of claim 23, wherein the security layer and the matcher run on separate computers.

31. A method of determining whether a patient is a candidate for a clinical trial, comprising:

serving a first questionnaire from a server to a patient through a patient interface;

receiving at the server a first set of patient eligibility data submitted by the patient in response to the first questionnaire;

sending the first set of patient eligibility data from the server to a security layer;

sending the first set of patient eligibility data from the security layer to a matcher;

in the matcher:

determining whether a match exists between the patient and the plurality of clinical trials by comparing the first set of patient eligibility data to a set of generic trial criteria generic to a plurality of clinical trials; and

returning generic match result information to the security layer;

if a match exists between the patient and the plurality of clinical trials:

serving a second questionnaire from the server to the patient through the patient interface;

receiving at the server a second set of patient eligibility data submitted by the patient in response to the second questionnaire;

sending the second set of patient eligibility data from the server to the security layer;

sending the second set of patient eligibility data from the security layer to the matcher;

in the matcher:

determining whether a match exists between the patient and the one clinical trial by comparing the second set of patient eligibility data to a set of specific trial criteria specific to one of the plurality of clinical trials; and

returning specific match result information to the security layer;

if a match exists between the patient and the one clinical trial:

sending information about the one clinical trial from the security layer to the server; and

serving the clinical trial information to the patient through the patient interface.

32. The system of claim 22, wherein the security layer sends the patient-specific data to the patient database for storage only after the system determines whether a match exists between the patient and the clinical trial.

33. The system of claim 19, wherein the security layer sends the patient's clinical trial eligibility data, but not other patient-specific data, to the matcher.

34. A system comprising:

a computer memory for storing information indicating whether notice of one or more clinical studies associated with a particular disease condition is desired and registration information that indicates at least a geographic location, said disease condition of interest, and contact information, wherein said memory further stores computer instructions for presenting a web page questionnaire to a user; and

means for storing in said memory responses to a questionnaire.

35. The system of claim 34, wherein said responses are used to determine whether to provide said user with notice of a clinical study associated with said particular disease condition.

36. The system of claim 34, wherein said disease condition of interest is selected from a list provided to said user.

37. The system of claim 34, wherein said questionnaire is a pre-examination questionnaire.

38. The system of claim 37, wherein said pre-examination questionnaire is a screening questionnaire.

39. The system of claim 37, wherein said pre-examination questionnaire is a pre-screening questionnaire.

40. The system of claim 34, wherein said questionnaire is a pre-screening questionnaire.

41. The system of claim 34, wherein said questionnaire is a screening questionnaire.

42. The system of claim 41, wherein said screening questionnaire is protocol specific.

43. The system of claim 34, wherein said questionnaire is designed for screening for clinically appropriate persons.

44. The system of claim 34, wherein said questionnaire requests information regarding inclusion/exclusion criteria.

***(9) Evidence Appendix***

None.

***(10) Related Proceedings Appendix***

None.